

IFU Lead Hands

INTENDED USE:Lead Hand is sold non-sterile and is used to position and immobilize a patient's hand during surgery.

INSTRUCTIONS FOR USE:

1. The Lead Hand should be cleaned and sterilized before use according to the parameters detailed below.
2. Place the lead hand on the surgical table and place the patient's hand on top of the lead hand.
3. Bend the wrist tabs over the patient's wrist and bend the immobilizer finger tabs over the patient's fingers as needed. The patient's hand should then be immobilized.
4. After the procedure, straighten the immobilizer's finger and wrist tabs and reprocess according to the sterilization instructions below.

CONTRAINDICATIONS:

There are no known contraindications associated with the Lead Hand.

CLEANING AND DISINFECTING:

Clean the lead hand prior to use using an automatic washer. It is not recommended to clean the lead hand manually.

1. Prepare an alkaline or neutral cleaning solution in accordance with the manufacturer's instructions.
2. If necessary, soak soiled lead hand according to the instructions for use for the cleaning solution for 10 minutes to loosen or remove soil.
3. Rinse the lead hand with de-ionized or demineralized water.
4. Drain water and rinse for a second time with de-ionized water.
5. Drain water and rinse for a third time with de-ionized water.
6. Disinfect using de-ionized water for 10 minutes at 94° C (201° F).
7. Dry for 30 minutes under hot air at 100° C (212° F).
8. Allow lead hand to cool at room temperature for 30 minutes.
9. Visually inspect the lead hand before sterilization to ensure the complete removal of soil.

10. Prepare item for sterilization in peel pouch, sterilization wrap or other approved sterilization packaging.

STERILIZATION:

The Lead Hand is provided non-sterile. Chemical sterilization is not recommended due to danger of corrosion.

Method Cycle

Temperature Exposure Time Dry Time

Dry Heat Up to 356° F

(180° C) 30 minutes -

Steam – Pre-Vac Up to 248° F

(120° C) 20 minutes 10 minutes

NOTE: Due to the nature of the material, oxidation may occur, leaving a film/coating on the lead hand that can be wiped away. The film/coating does not affect the performance of the hand immobilizer.

The Lead Hand has a life span and will require replacing if there are any signs of deterioration.

IMPORTANT:

The Lead Hand must not come in direct contact with open wounds or mucous membrane